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REMARKS

Claims 1-10 were present in the application as originally filed and new claims 11-17 were presented in a preliminary amendment filed with the application. Claims 16 and 17 were cancelled by amendment, and new claim 18 was added in a response dated 24 February 2004.

Telephone Interview

A second telephone interview between applicants' undersigned attorney and Examiner Isis Ghali was conducted on October 5, 2004. Applicants wish to express their appreciation for the Examiner's help in facilitating prosecution of the present application. During the interview, the teachings of U.S. Patent No. 5,779,632 to Dietz and U.S. Patent No. 6,150,459 to Mayes were discussed, along with possible claim amendments to overcome the rejections in the outstanding Office action.

Rejections Under 35 U.S.C. §112

Claims 1-15 and 18 are rejected under 35 USC §112, first paragraph, as failing to comply with the written description requirement, on the grounds that the terms "non-aqueous solvent" and "acrylic backbone" was not described in the specification as originally filed. The term "non-aqueous solvent" is deleted, and claims 1 now recites "an organic solvent" and claim 18 recites a "composition comprising an acrylic adhesive dissolved in an organic solvent". Support for the amendment may be found in the examples A-1 and 1-16, where preparation and use of acrylic polymer solutions is described. The term "acrylic backbone" is replaced with "acrylic adhesive", which is described in the specification on page 6, line 16-page 7, line 6 as being prepared by copolymerization of (meth)acrylate monomers with (meth)acrylate monomers that provide poly(ethylene oxide) functionality. It is believed that the rejection is hereby overcome.

Rejections under 35 U.S.C.§102

Claims 1, 2 and 18 are rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,779,632 to Dietz, *et al.* The rejection is traversed

Dietz relates to an adhesive composition prepared by photopolymerization of an aqueous microemulsion (Abstract) that may include polyethylene oxide acrylate monomers/oligomers (col. 10, lines 31-43). Claim 1 is now amended to recite "A composition for use in

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manufacturing an adhesive layer for transdermal preparation, said composition comprising an organic solvent, a drug to be delivered through skin and an acrylic adhesive, and said composition forming one phase, wherein the drug is hydrophilic or in a salt form and the acrylic adhesive has a poly (ethylene oxide) or poly (ethylene oxide) monomethyl ether side chain." The Dietz reference describes a general method to prepare a drug delivery device 100 by dissolving a therapeutic agent in a solvent and mixing the solution with a microemulsion (col. 32, lines 16-26). But a specific solvent that can be used in the general method is not mentioned. The only term mentioned in relation to a solvent is "a suitable solvent" and the suitable solvent is used to dissolve the therapeutic agent 108. In general, a hydrophilic drug or drug in a salt form, which are used in present invention, are insoluble in an organic solvent. Therefore, it is certain that when a hydrophilic drug or drug in a salt form are used as the therapeutic agent 108, an organic solvent, which is used in present invention, cannot be included in "the suitable solvent". In the present invention, the organic solvent was used not to dissolve the drugs, but to act as solvent for the polymer. The drugs were directly dissolved in the acrylic adhesive having a poly (ethylene oxide) or poly (ethylene oxide) monomethyl ether side chain (see Examples 1-16 of page 15-24). Furthermore, since, in US'632 to Dietz, a solution which is prepared by dissolving the therapeutic agent 108 and such optional excipients as are desired in a suitable solvent, should form a microemulsion, the solvent that can be used is very limited, and the only solvent actually used in US'632 is water. Therefore, applicants submit that the invention of claim 1 is not anticipated by US'632 to Dietz. In addition, the present invention is now distinguished more clearly from US'632 by the insertion of the term "one phase" in claim 1. It should be noted that one of the advantages of the present invention is avoidance of the instability that can result when adding a drug that is hydrophilic or in the form of a salt to a polymer to emulsion-type acrylic adhesives; formulating a drug in salt form into an emulsion polymer in an amount sufficient to have the desired therapeutic effect can break the emulsion, causing agglomeration of the polymer. In emulsion systems, loading of the drug in the adhesive composition may be limited. In contrast, high loadings of the drug may be achieved using single-phase compositions in the methods of the present invention. It is believed that the rejection of claim 1 and its dependent claims, claims 2-15, is hereby overcome.

Claim 18 is now amended to recite, in part, "providing an adhesive composition comprising an acrylic adhesive dissolved in an organic solvent, and forming one phase, the

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acrylic adhesive having a poly (ethylene oxide) or poly (ethylene oxide) monomethyl ether side chain". The Dietz reference describes preparation of drug delivery device 100 by dissolving a therapeutic agent in a solvent and mixing the solution with a microemulsion (col. 32, lines 16-26), as noted above; it does not disclose adding the therapeutic agent to a solution of the polymer in an organic solvent. In addition, the "one phase' limitation excludes emulsion compositions, such as those of Dietz from the claimed subject matter. One of the advantages of the present invention is avoidance of the demerits of emulsion-type acrylic adhesive, which has two phases consisting of oil phase and water phase. Therefore, Applicants submit that claim 18 as amended is not anticipated by Dietz. It is believed that the rejection is overcome.

Claims 1, 4, 5 and 18 are rejected under 35 U.S.C. §102(e) as being anticipated by U.S. Patent No. 6,150,459 to Mayes, *et al.* The rejection is traversed

Mayes relates to synthetic comb copolymers for use in various applications, including drug delivery (Abstract). For the drug delivery application, a therapeutic agent is attached to the side chain of the copolymer (col. 17, lines 18-24). The modified copolymer is administered orally or parenterally (col. 17, lines 34-36). Transdermal delivery is not mentioned. Applicant submits that because the therapeutic agent is attached to the polymer chain, Mayes's composition does not meet the requirements of the claims, as the therapeutic agent cannot be delivered through the skin. In addition, Mayes does not disclose application of the polymer/drug to a substrate or use of the polymer as an adhesive for a transdermal preparation, as required by claim 18. It is believed that the rejection is hereby overcome.

Rejections Under 35 U.S.C. § 103

Claims 1-15 and 18 are rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 5,779,632 to Dietz, *et al.*, or U.S. Patent No. 6,150,459 to Mayes, *et al.*, in view of U.S. Patent No. 5,865,792 to Ledger, *et al.* The rejections are traversed.

The teachings, and deficiencies of, Dietz and Mayes are discussed above. Ledger relates to an electrotransport device for delivering an ionized drug wherein the drug is contained in a reservoir (claim 1). The matrix of the reservoir may be composed of a hydrophilic polymer, including blends of polyethylene oxide with polyacrylic acid (col. 9, lines 15-35). The device

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may contain an adhesive applied to the face of the reservoir; composition of the adhesive is unspecified (col. 5, lines 60-67). Ledger does not mention acrylate polymers having a poly(ethylene oxide) or poly (ethylene oxide) monomethyl ether side chain.

There is no suggestion or motivation provided by the Ledger reference to modify the Dietz procedure for making a transdermal adhesive by using a single-phase composition instead of a microemulsion, since the advantages of the Dietz invention accrue from its bicontinuous structure (col. 4, line 32 - col. 5, line 2). Therefore, Applicants submit that the invention as claimed is not obvious over Dietz in view of Ledger. Similarly, there is no suggestion or motivation provided by the Ledger reference to modify the Mayes polymer so that the drug may be delivered through the skin, since attachment of the drug to the polymer is necessary for the oral and parenteral administration routes contemplated by Mayes. Therefore, Applicants submit that the invention as claimed is not obvious over Mayes in view of Ledger. It is believed that the rejection is hereby overcome.

Respectfully submitted,

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